K002473

NOV - 8 2000

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612-1601
Phone: (949) 250-3959
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Primary Contact:
Bonnie Bishop, Regulatory Affairs Manager
(949) 250-3959 ext. 4401

Alternate Contact:
Gary Reasoner, Director of Product Operations
(949) 250-3959 ext. 3387

The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.2300 "Cardiac Monitor" per DRT.

Common names for the WEC-7101A device include ECG Monitor, Cardiac Monitor and Heart Rate Monitor.

The predicate marketed device is the Nihon Kohden BSM-1102 Life Scope EC per 510(k) # K973918, commercial distribution certification dated 1/13/1998.

The WEC-7101A is intended for medical purposes to measure and display the heart rate and electrical signals produced by the heart. This device will be available for use by medical personnel on adults and children at least 3 years old and 22 lbs. The device is designed for quick ECG measurement and may be used in emergency and transport settings. This device does not provide alarms and is not intended for long term monitoring.

The device complies with IEC 601-1 subclause 56.3(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device.

The WEC-7101A device is not sterile.

The contact point of the device is comprised of well characterized materials used in other commercially available products. Therefore, good laboratory practice studies were not required per 21 CFR 58.

The WEC-7101A was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the WEC-7101A is substantially equivalent to the Nihon Kohden BSM-1102 Life Scope EC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2000

Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Re: K002473
Trade Name: WEC-7101A pocket ECG monitor
Regulatory Class: II (two)
Product Code: DPS
Dated: August 10, 2000
Received: August 11, 2000

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K002473

Device Name: WEC-7101A

Indications for Use:

The WEC-7101A is intended for medical purposes to measure and display the heart rate and electrical signals produced by the heart.

This device is designed for quick ECG measurement and may be used in emergency and transport settings including ambulances. The device will be available for use by medical personnel on adults and children at least 3 years old and 22 lbs.

This device does not provide alarms and is not intended for long term monitoring. The device is not intended as a sole basis for medical diagnosis.

Prescription Use Only

Division of Cardiovascular & Respiratory Devices
510(k) Number K002473